REMARKS

Claims 1-2, 5-7, 10-11, 21 and 23 are pending; claims 10 and 11 were withdrawn, leaving claims 1-2, 5-7, 21, and 23 under consideration. Applicants have amended claim 1 to insert a semicolon that was inadvertently omitted from the previous amendment. In addition, applications have amended claims 1, 2, 5-6, 10, and 21 to more clearly set forth the invention. Support for these amendments can be found throughout the application as filed, e.g., at page 3, lines 2-3; page 32 line 13 to page 33 line 10; page 33 line 29 to page 34 line 13; and the figures, e.g., fig. 3A, *inter alia*.

No new matter has been added.

Objection to the Specification

At pages 2-3 of the Office Action mailed March 22, 2007 (the "Office Action"), the specification was objected to for allegedly failing to comply with the sequence rules, specifically for failing to include a sequence identification number for the sequence set forth in figure 2C. However, Applicants wish to direct the Office's attention to the Preliminary Amendment that was filed on November 12, 2004, which includes an amendment to insert a sequence identifier into the description of Figure 2C. As the Examiner noted, this is sufficient ("the SEQ ID NO: may be referenced in the "Brief Description of Drawings." See MPEP 2422 & 2431). Applicants therefore request withdrawal of the objection to the specification. Applicants believe that the remainder of the specification is in compliance with the sequence rules, and request that the Examiner point out any other deficiencies noted.

Rejection under 35 U.S.C. 112, first paragraph

Claims 1-7, 10-11 and 21-23 were rejected at pages 3-6 of the Office Action because

> ... the specification, while being enabling for providing a D4Z4 binding element with a specific sequence localized in region 4q35 of human chromosome 4, contacting the D4Z4 binding element with a test compound and determining whether the test compound interacts with the D4Z4 binding element, does not reasonably provide enablement for providing "a D4Z4 binding element," contacting the D4Z4 binding element with a test compound and determining whether the test compound interacts with the D4Z4. The

> specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Further, the specification is not enabling for determining the level of expression of recited genes, generic genes or named.

See page 3 of the Office Action. Applicants respectfully traverse.

The identity of a "D4Z4 binding element" was well known in the art at the time of filing, and Applicants have amended independent claims 1, 10, and 21 to recite a "a D4Z4 binding element comprising DNA comprising one or more 4q35 D4Z4 repeats." The 4q35 D4Z4 repeats were well known in the art at the time of filing. The full sequence of each repeat was determined and publicly available in 1994 (see Hewitt et al., Hum. Mol. Genet. 3(8):1287-95 (1994), abstract attached, referenced in Winokur et al., Hum. Mol. Genet. 5(10):1567-1575 (1996), which was cited by the Office and is also incorporated by reference in the present application). The claims specify that the binding element can have one or more such repeats. Thus, one of skill in the art would readily have understood what constitutes the sequence of a 4q35 D4Z4 repeat, and have been able to make and use a D4Z4 binding element as recited in claims 1, 10, and 21, with no more than routine experimentation, using standard molecular biological techniques.

At page 5, the Office Action stated that

> The art (in this case, post filing date) indicates many other genes in the region of 4q35 (Blair et al, 2005) than are described in the disclosure or in the prior art. See Table 1, Blair et al. Thus, the specification could not have been enabling for a generic "4q35 gene" at the time of filing. The claims also recite measuring expression of FSHD region genes, such as FRG1, etc. However there is no description of such genes, their introns/exons, splice sites, promoter regions, and spice forms. Therefore one skilled in the art would not know what is being measured nor how to measure it.

While Applicants do not concede that the recitation of a genus of 4q35 genes is not enabled, Applicants have amended claim 1 to recite "a cell that expresses FSHD region gene 1 (FRG1)." The specification incorporates by reference van Deutekom et al., "Identification of the first gene (FRG1) from the FSHD region on human chromosome 4q35," Hum. Mol. Genet. 5, 581–590 (copy submitted previously), which describes the cloning of the FRG1 cDNA and gene, provides

the sequence of the FRG1 promoter and cDNA (see page 584), and provides the GenBank Accession number for the FRG1 gene: L76174 (see page 581).

In light of these amendments and arguments, Applicants submit that, for at least these reasons, claim 1 as amended is amply enabled.

Claims 1-7, 10-11 and 21-23 were further rejected at pages 6-7 of the Office Action as allegedly failing to comply with the written description requirement. In particular, the recitation of "a generic D4Z4 binding element, a generic 4q35 gene, and FRG1, FRG2, and ANT1 genes" was noted as lacking "a closed structural definition."

While applicants do not concede that the application as filed lacks written description support for the genus of D4Z4 binding elements and 4q35 genes, to expedite prosecution applicants have amended independent claims 1, 10, and 21, to specify "a D4Z4 binding element comprising DNA comprising one or more 4q35 D4Z4 repeats." In addition, applicants have amended claim 2 to recite "a cell that expresses FSHD region gene 1 (FRG1)." As noted above, the sequences of FRG1 and the 4q35 D4Z4 repeat were well known in the art at the time of filing. Thus, one of skill in the art could readily identify suitable sequences for use in the claimed methods.

"There is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure," Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. May 26, 2006). Applicants submit that the specification provides sufficient specific structural information that one of skill in the art would readily recognize that the inventors had possession of the claimed invention.

For at least these reasons, Applicants submit that the claims satisfy the requirements of 35 U.S.C. §112, first paragraph, and respectfully request reconsideration and withdrawal thereof.

Rejection under 35 U.S.C. 102

Claims 1-2 and 7 were rejected at page 8 of the Office Action as allegedly anticipated by Winokur et al., 1996.

While not conceding that the previously pending claims were anticipated by Winokur et al., Applicants have amended claim 1 to incorporate the limitations of claim 3, and have amended claims 10 and 21 to make them independent, with all the limitations of claim 1. Applicants submit that the pending claims are novel and non-obvious over Winokur et al., and request withdrawal of the rejection under 35 U.S.C. 102.

Conclusion

For at least the reasons set forth herein, Applicants submit that the pending claims are patentable, and request prompt notification thereof. If the Examiner feels that it would further the examination of the present application, he is invited to telephone the undersigned at (617) 956-5985.

The fees in the amount of $180 for the information disclosure statement and $225 for the petition for extension of time are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 07917-180001.

Respectfully submitted,

Date: Aug. 15, 2007

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